

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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IN RE TELIK, INC.  
SECURITIES LITIGATION

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) Civil Action No. 07-cv-04819 (CM)  
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) **AMENDED CLASS ACTION COMPLAINT**  
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**NATURE OF THE ACTION AND OVERVIEW**

1. Lead Plaintiff, the Policemen's Annuity and Benefit Fund of Chicago, and Plaintiffs Ramesh K. Mehan, RML Limited, Ramesh K. Mehan Irrevocable Children's Trust, Joel K. Mehan Irrevocable Trust, Sheila G. Mehan Irrevocable Trust, Renee Mehan Family Trust, Neal D. Mehan Irrevocable Trust, Rahul D. Mehan and Ramesh K. Mehan Family Trust (the "Mehan Group") (Lead Plaintiff and the Mehan Group are collectively referred to herein as "Plaintiffs"), allege the following based upon the investigation by Plaintiffs' counsel, which included, among other things: a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Telik, Inc. ("Telik" or the "Company"), securities analysts' reports and advisories about the Company, and information readily available on the Internet. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

2. This is a federal class action on behalf of purchasers of the common stock of Telik, who purchased or otherwise acquired Telik's common stock between February 19, 2004 and June 4, 2007, inclusive (the "Class Period"), including purchasers in the Company's January 28, 2005 stock offering (the "2005 Offering"), seeking to pursue remedies under the Securities

Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

3. Telik is a biopharmaceutical company that works to develop and commercialize innovative small molecule drugs to treat diseases. The Company's most advanced drug development candidate is TELCYTA (TLK286), a tumor-activated small molecule designed to be activated in cancer cells. Throughout the Class Period, the Company conducted multiple clinical trials to evaluate the effectiveness of TELCYTA, and reported positive interim results to investors.

4. Before a new drug can be marketed in the United States, it must be approved by the Federal Drug Administration ("FDA"), and only after a lengthy period of clinical trials which are divided into several phases:

Done at hospitals and research centers around the country, clinical trials are conducted in phases. Phase 1 trials try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects. Usually, a small number of healthy volunteers (between 20 and 80) are used in Phase 1 trials.

Phase 2 trials include more participants (about 100-300) who have the disease or condition that the product potentially could treat. In Phase 2 trials, researchers seek to gather further safety data and preliminary evidence of the drug's beneficial effects (efficacy), and they develop and refine research methods for future trials with this drug. If the Phase 2 trials indicate that the drug may be effective--and the risks are considered acceptable, given the observed efficacy and the severity of the disease--the drug moves to Phase 3.

In Phase 3 trials, the drug is studied in a larger number of people with the disease (approximately 1,000-3,000). This phase further tests the product's effectiveness, monitors side effects, and, in some cases, compares the product's effects to a standard treatment, if one is already available. See [http://www.fda.gov/fdac/features/2003/503\\_trial.html](http://www.fda.gov/fdac/features/2003/503_trial.html).

5. Telik initiated Phase 2 clinical trials of TELCYTA in colorectal, ovarian and non-small cell lung cancers in the first half of 2001 and continued them throughout the Class Period.

Telik initiated Phase 3 clinical trials of TELCYTA in the beginning of the Class Period in March of 2003. These Phase 3 trials consisted of three separate testing arms called ASSIST (Assessment of Survival In Solid Tumors) 1, 2, and 3.

6. ASSIST 1 was a 440 patient multinational, randomized study designed to evaluate TELCYTA as compared to the active control agents liposomal doxorubicin or topotecan in the third-line therapy of platinum resistant ovarian cancer. ASSIST 2 was a 520 patient multinational, randomized study designed to evaluate TELCYTA as compared to gefitinib in the third-line therapy of advanced non-small cell lung cancer. ASSIST 3 was a 244 patient randomized trial conducted in the U.S. designed to demonstrate a statistically significant improvement in overall tumor response to the combination of TELCYTA plus carboplatin compared to liposomal doxorubicin in the second-line treatment of platinum resistant ovarian cancer. The primary “endpoint,” or goal, of ASSIST 1 and 2, was survivability. The primary endpoint of ASSIST 3 was “objective response” to TELCYTA, *i.e.*, reduction in tumor size, with a secondary endpoint of survivability.

7. During conduct of a clinical trial, which may last for several years, sponsor companies, such as Telik, or any sponsor company proxy (such as a data management committee) must periodically report interim data to the FDA. Here, the Telik Defendants (defined below) acknowledged that that they received interim data concerning both the Phase 2 and Phase 3 clinical trials throughout the Class Period. Indeed, the Telik Defendants repeatedly updated the market on the findings of the Phase 2 interim analyses. At various oncological conferences, in press releases, and in analysts’ conference calls throughout the Class Period, the Telik Defendants repeatedly touted favorable interim Phase 2 clinical trial results for TELCYTA, publicly stating that it had demonstrated significant anti-tumor activity and a favorable impact on

survival. As a consequence of these glowing reports, Telik common stock reached a Class Period high of \$29.04 per share. In addition, in January 2005, Telik engaged in a follow-up offering of 8,050,000 shares of common stock that was completed in February 2005. Net proceeds to the Company from that offering were approximately \$142.2 million.

8. Unbeknownst to the investing public, however, even as they were issuing highly positive statements about the interim results of the Phase 2 clinical trials, the Telik Defendants had received, and were receiving, interim data from the ASSIST 1 and 2 Phase 3 clinical trials which contradicted those results. As alleged more fully below, interim data from the Phase 3 trials showed that TELCYTA did not, in fact, improve survival rates, but rather that patients treated with TELCYTA actually died *sooner* than the control groups who did receive the drug. In addition, the Telik Defendants failed to disclose that they had received interim information that the ASSIST 3 Phase 3 clinical trial had been compromised by data irregularities, which rendered it useless for submission to the FDA.

9. The truth was partially disclosed on December 26, 2006 when, in stark contrast to their positive Class Period statements, the Telik Defendants stunned the market by announcing that *TELCYTA had failed all three of its Phase 3 clinical trials*. With respect to ASSIST 1, the Company announced that “TELCYTA did not achieve a statistically significant improvement in overall survival, the primary endpoint.” With respect to ASSIST 2, the Company announced that TELCYTA “did not achieve its primary endpoint of demonstrating a statistically significant improvement in overall survival for TELCYTA as compared to the active controls.” Additionally, the Company disclosed that in the third Phase 3 clinical trial, ASSIST 3, approximately 25% of the patients were prematurely discontinued from the assigned study treatment, invalidating that trial.

10. On this news, shares of the Company's stock declined \$11.49 per share, or over 70%, to close on December 26, 2006 at \$4.77 per share, on unusually heavy trading volume.

11. Although the Telik Defendants had disclosed that TELCYTA failed all three Phase 3 clinical trials, they failed to disclose the actual magnitude of that failure for over five months. Indeed, from December 2006 until June 2007, the Telik Defendants continued to make positive statements about the purported efficacy of TELCYTA based on various studies and interim data from the Phase 2 clinical trials. Then, on June 3, 2007, the Company released the results of its ASSIST-1 trial at the annual meeting of the American Society of Clinical Oncology ("ASCO"), revealing for the first time the full extent of the adverse results of its TELCYTA Phase 3 clinical trials. In stark contrast to their positive statements, the Telik Defendants revealed that participants in the study groups who received TELCYTA, actually *died five months sooner*, on average, than those in the control groups who did not receive the drug (8.5 months compared to 13.6 months for the control group). In a separate announcement, the Company further disclosed that patients in the non-small cell lung cancer ASSIST 2 trial that had received TELCYTA had a median survival rate of 4.6 months compared to a median survival rate of 6.1 months for the control group that had not received TELCYTA.

12. The following day, June 4, 2007, the FDA placed a clinical hold on the Company's Investigational New Drug Application for TELCYTA, which was initiated by the FDA following the presentation of TELCYTA Phase 3 clinical trial results. The effect of this clinical hold stopped new patient enrollment in TELCYTA clinical trials, and the Company was prohibited from administering additional doses of the drug to those patients already enrolled in the trials. Following the Company's disclosure and the FDA announcement, shares of the

Company's stock declined an additional 41% to close on June 5, 2007 at \$3.42 per share, on unusually heavy trading volume.

13. The Telik Defendants' materially misleading statements and omissions artificially inflated the price of Telik common stock throughout the Class Period, during which the Telik Defendants raised over \$150 million in an equity offering. When the full truth about TELCYTA was finally disclosed at the end of the Class Period, the artificial inflation in the market value of Telik common stock was eliminated. Plaintiffs and the other members of the Class who purchased shares of Telik common stock at artificially inflated prices throughout the Class Period, in ignorance of the adverse information about TELCYTA to which Defendants were privy, were damaged thereby.

#### **JURISDICTION AND VENUE**

14. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l and 77o), and under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act (15 U.S.C. § 77v), Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. § 1331.

16. Venue is proper in this Judicial District pursuant to Section 22 of the Securities Act and pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this Judicial District.

Additionally, the Company's Offering was actively marketed in this Judicial District. The Underwriter Defendants (defined below) all have offices in this District.

17. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

18. Lead Plaintiff Policemen's Annuity and Benefit Fund of Chicago purchased Telik common stock at artificially inflated prices during the Class Period and has been damaged thereby.

19. Plaintiff Mehan Group, comprised of Ramesh K. Mehan, RML Limited, Ramesh K. Mehan Irrevocable Children's Trust, Joel K. Mehan Irrevocable Trust, Sheila G. Mehan Irrevocable Trust, Renee Mehan Family Trust, Neal D. Mehan Irrevocable Trust, Rahul D. Mehan and Ramesh K. Mehan Family Trust, also bought Telik stock during the Class Period and suffered injury thereby.

20. Defendant Telik is a Delaware corporation with its principal place of business located at 3165 Porter Drive, Palo Alto, California.

21. Defendant Michael M. Wick, M.D., Ph.D. ("Wick") was, at all relevant times, the Company's President, Chief Executive Officer ("CEO"), and Chairman of the Board of Directors.

22. Defendant Cynthia M. Butitta ("Butitta") was, at all relevant times, the Company's Chief Financial Officer ("CFO"), Chief Operating Officer ("COO"), and Principal Accounting Officer.

23. Defendants Wick and Butitta are collectively referred to hereinafter as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Telik’s reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each Defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material, non-public information available to them, each of these Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendants.

24. Telik and the Individual Defendants are collectively referred to herein as the “Telik Defendants.”

25. Defendant UBS Securities LLC (“UBS”) is an investment banking house with offices in this District. Defendant UBS was an underwriter and Lead Manager for the Company’s January 2005 Offering.

26. Defendant Lehman Brothers Inc. (“Lehman”) is an investment banking house with offices in this District. Defendant Lehman was an underwriter and Co-Manager for the Company’s January 2005 Offering.



27. Defendant J.P. Morgan Securities Inc. ("JP Morgan") is an investment banking house with offices in this District. JP Morgan was an underwriter and Co-Manager for the Company's January 2005 Offering.

28. Defendants UBS, Lehman, and JP Morgan are collectively referred to herein as the "Underwriter Defendants." The Underwriter Defendants served as underwriters, financial advisors, and assisted in the preparation of the Company's January 2005 Offering.

## **BACKGROUND**

### **I. The Regulatory Framework**

29. Telik describes itself as a biopharmaceutical company working to discover, develop and commercialize innovative small molecule drugs to treat serious diseases, including cancer and diabetes. Telik's lead product candidate is TELCYTA or TLK286, which the Company describes as a small molecule tumor-activated cancer drug that is being evaluated initially to treat cancers that are resistant to standard chemotherapy drugs. The Company described TELCYTA as working by binding to glutathione S-transferase P1-1, or GST P1-1, a protein that is elevated in many human cancers, including ovarian, non-small cell lung, lymphoma, leukemia, pancreas, colorectal, breast and other types of cancer. GST P1-1 levels are often further elevated following treatment with many standard chemotherapeutic drugs and this elevation is associated with the development of resistance to these drugs. According to Telik, when TELCYTA binds to GST P1-1 inside a cancer cell, a chemical reaction occurs, releasing a fragment of TELCYTA that causes programmed cancer cell death, or apoptosis.

30. By the start of the Class Period, the Company reported that TELCYTA had been evaluated, and was being evaluated, in numerous clinical trials. Under governing regulations promulgated by the FDA, companies sponsoring clinical trials, such as Telik, are required to

monitor clinical drug trials, review and evaluate evidence relating to the safety and effectiveness of the new drug candidate, and submit annual reports to the FDA regarding the progress of the investigation. In pertinent part, 21 CFR §312.56, "Review of On-Going Investigations," provides:

The sponsor shall monitor the progress of all clinical investigations being conducted under its IND [investigational new drug application].

\* \* \*

The sponsor shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator. The sponsors shall make such reports to FDA regarding information relevant to the safety of the drug as are required under 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with 312.33.

*Id.*

31. 21 CFR § 312.33, "Annual reports," describes the information that sponsor companies are required to submit to the FDA on an annual basis:

A sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes:

(a) Individual study information. A brief summary of the status of each study in progress and each study completed during the previous year. The summary is required to include the following information for each study:

(1) The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.

(2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; *the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.*

(3) If the study has been completed, or if interim results are known, a brief description of any available study results.

(b) Summary information. Information obtained during the previous year's clinical and nonclinical investigations, including:

- (1) A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.
  - (2) A summary of all IND safety reports submitted during the past year.
  - (3) A list of subjects who died during participation in the investigation, with the cause of death for each subject.
  - (4) A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.
  - (5) A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, information from controlled trials, and information about bioavailability.
  - (6) A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.
  - (7) A summary of any significant manufacturing or microbiological changes made during the past year.
- (c) A description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The general investigational plan shall contain the information required under 312.23(a)(3)(iv).
- (d) If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.
- (e) A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.
- (f) A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.
- (g) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

*Id.* [Emphasis added].

32. In compliance with FDA regulations, Telik received, analyzed, and reported interim data from the TELCYTA clinical trials to the FDA prior to, and throughout, the Class Period. Significantly, Telik conducted extensive analyses of the clinical trial interim data it received, stating that the TELCYTA clinical trials were specifically designed to provide for “interim looks” to exploit the opportunity for accelerated approval by the FDA. Moreover, the Telik Defendants repeatedly issued public statements announcing positive interim results of the various clinical trials of TELCYTA prior to, and during, the Class Period.

33. For example, in May 2002, at the American Society of Clinical Oncology annual meeting, Telik announced positive interim results from multicenter Phase 2 trials of TELCYTA in ovarian and non-small cell lung cancer. According to Telik, in the ovarian cancer trial, TELCYTA demonstrated significant single agent antitumor activity, including multiple objective tumor responses and prolongation of expected survival in patients who were unresponsive to standard treatments. The Company also reported that in the non-small cell lung cancer trial, TELCYTA treatment was associated with disease stabilization and an improvement in expected survival. These Phase 2 trials were the bases for the more expansive Phase 3 TELCYTA clinical trials initiated in 2003.

## **II. The Phase 3 Trials and Continued Positive Interim Results**

34. On March 27, 2003, the Company issued a press release entitled “Telik Initiates Phase 3 Registration Trial of TLK286 in Ovarian Cancer Patients.” In that release, the Company stated, in pertinent part:

Telik, Inc. announced the initiation of a randomized, controlled Phase 3 registration trial of TLK286 administered as a single agent in ovarian cancer patients whose disease has progressed following platinum-based chemotherapy and one second-line treatment.

The multinational trial, designated the ASSIST-1 (ASsessment of Survival In Solid Tumors-1) trial, is expected to enroll approximately 440 women.

Patients will be randomized to a TLK286 treatment group, or to a control group receiving either Doxil® or Hycamtin®, drugs that are commonly used in the third-line ovarian cancer setting. The study is designed to evaluate whether TLK286 treatment reduces the risk of death, leading to an increase in survival, as compared to the control group treatments.

Results from a Phase 2 single agent study of TLK286 in ovarian cancer were presented at the American Society of Clinical Oncology meeting in May 2002 and at the EORTC/NCI/AACR meeting in November 2002. In this trial, objective tumor responses were observed and median patient survival was estimated at 17 months by Kaplan-Meier analysis.

“Ovarian cancer has the highest mortality rate of all gynecologic malignancies. There is an urgent need for new treatment alternatives since approximately 75% of new cases of ovarian cancer are diagnosed at an advanced stage,” said Gail L. Brown, M.D., senior vice president and chief medical officer. “The objective responses and survival benefit observed with TLK286 in our Phase 2 ovarian cancer trial, the clinical activity reported in other cancers, including non-small cell lung, breast and colorectal, as well as the tolerability profile seen in more than 350 patients, provide a strong foundation for this Phase 3 trial.”

35. As the ASSIST-1 Phase 3 trial of TELCYTA was commencing, the Telik Defendants continued to issue statements about the positive interim finding concerning the drug. Thus, on June 1, 2003, the Company issued a press release entitled “Telik Announces Confirmatory Results from Second Phase 2 Trial of TELCYTA™ in Advanced Non-Small Cell Lung Cancer.” In that release, the Company reported positive interim results from a Phase 2 clinical trial involving non-small cell lung cancer. The Company, in pertinent part, stated:

Telik, Inc. **announced positive interim results** from a second Phase 2 trial which confirm the clinical activity of TELCYTA™ (TLK286) administered as a single agent in the treatment of patients with non-small cell lung cancer who have failed platinum-containing regimens. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

**Interim results from this trial show an 8% objective response rate** (one partial response by the RECIST criteria), one minor response (8%) and a 67% overall disease stabilization rate. Median duration of stable disease is greater than 4.5 months and ongoing. Median survival has not yet been reached. TELCYTA™ continues to be well-tolerated, with the most common adverse events in this trial categorized as Grade 1 or 2

(mild to moderate). There were few Grade 3 and no Grade 4 adverse events. Thirty-three patients with Stage IIIB or IV non-small cell lung cancer were evaluable for survival and 12 patients were evaluable for tumor response at the time of interim analysis. Half had failed prior platinum therapy and two-thirds also were resistant to paclitaxel.

“Advanced, chemotherapy-resistant non-small cell lung cancer patients have a predictably poor prognosis, and published clinical trials with second- and third-line agents for the disease have shown low response rates and median survival times from four to six months,” said Gail L. Brown, M.D., senior vice president and chief medical officer. “In the earlier Phase 2 trial of TELCYTA™ in non-small cell lung cancer, median survival was significantly improved over that expected for these patients. **We are encouraged that the objective responses and high disease stabilization rate may translate to a survival advantage in this ongoing trial.**”

Telik plans to initiate a registration Phase 3 trial of TELCYTA™ for the treatment of advanced non-small cell lung cancer.

**In Phase 2 trials, TELCYTA™ has demonstrated clinical activity in ovarian, breast and colorectal cancer, in addition to non-small cell lung cancer.** A high proportion of these tumors express GST P1-1, which activates TELCYTA™ within the tumor. [Emphasis added.]

36. On June 1, 2003, the Company also issued a second press release, entitled “Telik Announces Confirmatory Results from Second Phase 2 Trial of TELCYTA™ (TLK286) in Advanced Ovarian Cancer.” This release announced positive interim findings involving TELCYTA administered as a single agent in patients with ovarian cancer – the same parameters as the ASSIST-1 Phase 3 clinical trial. In pertinent part, the release stated:

Telik, Inc. (Nasdaq: TELK) announced **positive interim results** from a second Phase 2 clinical trial of TELCYTA™ (TLK286) administered as a single agent in women with platinum refractory or resistant ovarian cancer, that confirm the previous results of a previous Phase 2 trial in this patient population. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

**The interim results show a 17% objective response rate (three partial responses by RECIST criteria) and 56% overall disease stabilization rate in women with advanced, platinum refractory or resistant ovarian cancer.** Responses were accompanied by clinical symptom improvement. Median duration of stable disease is greater than six months

and ongoing. Median survival has not yet been reached. TELCYTA™ continues to be well-tolerated, with the most common adverse events categorized as Grade 1 or 2 (mild to moderate). Grade 3 adverse events were infrequent, and no Grade 4 adverse events were reported.

**The interim analysis** is based on 33 patients evaluable for survival and 18 patients evaluable for tumor response. All of the patients were either refractory or resistant to platinum, and 82% were resistant to paclitaxel and additional salvage therapies.

“These results confirm the clinical activity reported in the previous Phase 2 trial of TELCYTA™ in advanced ovarian cancer and support the ongoing Phase 3 registration trial of TELCYTA™ in the third-line ovarian cancer setting,” said Gail L. Brown, M.D., senior vice president and chief medical officer. **“The interim results of this trial are comparable with those of the first ovarian cancer trial at a similar stage. This is encouraging because, in our earlier Phase 2 trial, clinical responses correlated with improved overall median survival.** The efficacy, favorable toxicity profile and non-overlapping toxicities reported with TELCYTA™ now observed over a wide range of patient drug exposure, facilitate its use both as a single agent and in combination regimens in less advanced patients.”

“Further, we are pleased to report that the ovarian cancer patient in our earlier Phase 2 trial, whose complete response following TELCYTA™ treatment was first reported at the 2002 ASCO meeting, remains in complete remission and off all treatment for ovarian cancer,” Dr. Brown said. “This durable, long-term complete response is particularly encouraging because her disease was refractory to platinum therapy.” [Emphasis added.]

37. The Telik Defendants also issued public statements concerning positive interim results of the Phase 2 clinical trials of TELCYTA on June 30, 2003; July 30, 2003; August 14, 2003; and October 29, 2003.

38. On September 3, 2003, the Company issued a press release entitled “Telik Announces FDA Fast Track Designation for TELCYTA™.” Therein, the Company, in relevant part, stated:

Telik, Inc. (Nasdaq: TELK) announced that the U.S. Food and Drug Administration has granted Fast Track designation for TELCYTA™ (TLK286) for third line therapy in patients with platinum refractory or resistant ovarian cancer.



“Fast Track designation is a recognition by the FDA of the serious unmet medical need faced by women with platinum refractory or resistant ovarian cancer, and the potential of TELCYTA™ to address that need,” said Gail L. Brown, M.D., senior vice president and chief medical officer. A randomized Phase 3 registration clinical trial with TELCYTA™ is in progress for third line therapy in patients with platinum refractory or resistant ovarian cancer.

39. Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

40. On October 1, 2003, the Company issued a press release entitled “Telik Announces Successful Completion of FDA Special Protocol Assessment TELCYTA™.” In that release, the Company stated, in pertinent part:

Telik, Inc. (Nasdaq: TELK) announced that the Phase 3 protocol for TELCYTA™ (TLK286) in non-small cell lung cancer (NSCLC) has successfully completed Special Protocol Assessment (SPA) review by the U.S. Food and Drug Administration.

The trial, designated ASSIST-2 (Assessment of Survival In Solid Tumors-2), will enroll approximately 500 patients with platinum refractory or resistant NSCLC who will be randomized to receive either TELCYTA™ or Iressa® (gefitinib) for the third-line treatment of NSCLC. The study is designed to evaluate whether TELCYTA™ treatment leads to an increase in survival as compared to the control treatment. The first Phase 3 TELCYTA™ protocol, for the ongoing ASSIST-1 trial of TELCYTA™ in women with platinum refractory or resistant ovarian cancer, previously underwent successful SPA review.

41. On October 29, 2003, the Company issued a press release entitled “Telik Announced Proposed Equity Offering.” Therein, the Company, in relevant part, stated:

Telik, Inc. (Nasdaq: TELK) announced plans to offer 6,000,000 shares of common stock in an underwritten public offering under its existing shelf registration statement. Five million of the shares are expected to be offered by the company, and 1,000,000 shares are expected to be offered by a corporate selling stockholder. In addition, the underwriters will have an option to purchase from the company up to an additional 900,000 shares to cover over-allotments, if any.



42. In connection with this offering, the Company filed a Prospectus on November 6, 2003. The Prospectus indicated that the Company now sought to offer 6.5 million shares of stock for sale to the public at \$20.00 per share, and a selling stockholder sought to offer an additional 1 million shares of stock for sale to the public. Additionally, the underwriter over-allotment was increased to an additional 1.125 million shares for sale. The offering was a financial success for the Company, as it was able to raise over \$152.5 million in gross proceeds.

43. On December 2, 2003, the Company issued a press release entitled "TELIK Announced FDA Fast Track Designation for TELCYTA™ for Non-Small Cell Lung Cancer." Therein, the Company, in relevant part, stated:

Telik, Inc. (Nasdaq: TELK) announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for TELCYTA™ (TLK286) for third line therapy for locally advanced or metastatic non-small cell lung cancer. The FDA previously granted Fast Track designation for TELCYTA™ for third line therapy in patients with platinum refractory or resistant ovarian cancer.

Fast Track programs are designed to facilitate the development and expedite the review of new drugs that demonstrate the potential to treat serious or life-threatening conditions and address unmet medical needs.

### **ALLEGATIONS UNDER THE EXCHANGE ACT**

#### **I. Class Period Events and the Materially False and Misleading Statements**

44. On February 19, 2004, the Company issued a press release entitled "Telik Announces Fourth Quarter and Year-End 2003 Financial Results." With respect to TELCYTA, the press release, in relevant part, stated:

Highlights during 2003 included:

**TELCYTA™**

- Telik reported positive, confirmatory results from additional Phase 2 studies of TELCYTA™ administered as a single agent in ovarian and non-small cell lung cancer at the American Society of Clinical Oncology meeting in June.

45. The Telik Defendants' statements concerning the positive results from the Phase 2 studies of TELCYTA administered as a single agent in ovarian cancer, were materially misleading. The February 19, 2004 press release specifically references and reiterates the conclusions first presented to ASCO in June 2003, which was the subject of a June 1, 2003, press release that included statements about improved overall median survival for TELCYTA patients versus the control arm. *See* ¶ 35. By February 19, 2004, however, when the Telik Defendants made the statements reiterating the positive results first announced in June 2003, they knowingly or recklessly failed to disclose that they had received, and were receiving contrary interim data, including event (death) rate data, from the Phase 3 ASSIST-1 clinical trials of TELCYTA that showed that there was **no** improvement in overall median survival for ovarian cancer patients who received TELCYTA as a single agent as compared to the control arm. Indeed, as was ultimately disclosed at the end of the Class Period, the patients receiving TELCYTA as a single agent had a median survival rate of 8.5 months as compared to a median survival rate of 13.5 months for the patients in the control arm who did not receive TELCYTA.

46. As alleged above, pursuant to 21 CFR § 312.56, Telik was required to "review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the [clinical trial] investigator" for use in its annual reporting to the FDA. *See* ¶ 30. In addition, as alleged below in ¶ 49, during a conference call with analysts and investors on the same day that the press release was issued, Defendant Wick expressly stated that clinical trial

data was available to the Telik Defendants based on "interim looks." Thus, at the time that the Telik Defendants made the statements concerning the positive interim results of the Phase 2 trial, they had contrary information from the Phase 3 ASSIST-1 trial that showed that those statements were materially false and misleading.

47. On February 19, 2004, the Company also conducted an earnings conference call with financial analysts and investors. During this call, Defendant Wick confirmed that "[t]he Phase III trial on ovarian cancer is well underway." Defendant Wick also confirmed that the Telik Defendants were receiving interim data from that trial on an on-going basis:

Well, you know, we designed this trial with all the bells and whistles.... You know, I think we've given the same guidance we've given right along -- we're committed to finishing this trial. We've built in every opportunity to have success. We will communicate with Wall Street if there are any -- you know -- if the independent data monitoring committee makes any substantive recommendations, you know, there can be lots of them along the way. You know, if the assumptions on the trial were not borne out that we agreed to, we might have to adjust our trial. We certainly don't expect -- nor have we seen any evidence of safety concerns for Telcyta, which is typically an issue. **But insofar as any interim looks don't change our original guidance, we won't communicate them. Insofar as they do, we will. . . .**

[Emphasis added.]

48. On April 29, 2004, the Company conducted an earnings conference call with financial analysts and investors. During this call, Defendant Wick stated:

Phase 3 trials follow the comprehensive successful Phase 2 clinical development program, now having treated hundreds of patients with thousands of doses, including two confirmatory single-agent trials, each in ovarian and non-small cell lung cancer, as well as trials in breast and colorectal cancer. **Across these trials, Telcyta has demonstrated significant anti-tumor activity, continued outstanding tolerability, and a favorable impact on survival, compared to expected, in those very advanced patients.** We have previously reported data for these trials at ASCO and other scientific meetings, and now are in the process of publishing them in peer review journals. [Emphasis added.]

49. During that same call, Defendant Butitta confirmed that the TELCYTA clinical trials were specifically designed so that interim data was available to enable Telik to seek accelerated FDA approval of TELCYTA if warranted:

Thanks, Mike. ... the opportunity for continued growth and value for our shareholders through the development of Telcyta and Telintra is very significant. Since the last call we have initiated, as planned, the Phase 3 registration trials for single-agent Telcyta in non-small cell lung cancer, and we also initiated a front-line non-small cell lung cancer trial using Telcyta in combination with Cisplatin. Our guidance on timing for the Phase 3 trials remains unchanged. We have over 150 sites activated in the ovarian trial and we expect enrollment to be completed later this year. We also expect to complete accrual in the lung cancer trial within the year. Since both trials are event-driven, the timing for having results is not precisely predictable. **We design these trials with interim looks to provide opportunities for accelerated approval, although we are prepared to complete the trials and anticipate filing the NDA in the second half of '05.** [Emphasis added.]

Defendant Wick reiterated Butitta's comments concerning the availability of interim data to Telik:

We think it's important to offer our investors, our shareholders, every opportunity to participate in this. **So this is a state-of-the-art trial, with all in scale points out the bells and whistles. They include interim looks,** independent data safety monitoring boards. Typically, these are based on fractions of events occurring. As you know, the endpoints are response rates, TTPN, and death, are the typical issues. And Cindy said earlier, we began the trial, but we'll only communicate with the street if any of those interim looks change in a material way our guidance for that trial, either in terms of size, of timing, or that's finished. Okay, and so far, none of those have occurred. [Emphasis added.]

50. Defendants Wick's statements concerning the positive results from the Phase 2 studies of TELCYTA administered as a single agent in ovarian cancer and non-small cell lung cancer quoted in paragraph 48, were materially misleading. Specifically, Defendant Wick knowingly or recklessly failed to disclose the Telik Defendants had received and were continuing to receive interim data, including event (death) rate data, from the Phase 3 ASSIST-1

and ASSIST-2 clinical trials of TELCYTA that showed that there was **no** improvement in overall median survival for ovarian cancer patients or non small cell lung cancer patients, respectively, who received TELCYTA as a single agent as compared to the control arms. Indeed, as was ultimately disclosed at the end of the Class Period, the ovarian cancer patients receiving TELCYTA as a single agent had a median survival rate of 8.5 months as compared to a median survival rate of 13.5 months for the patients in the control arm who did not receive TELCYTA. The non-small cell lung cancer patients who had received TELCYTA had a median survival rate of 4.6 months compared to a median survival rate of 6.1 months for the control group that had not received TELCYTA.

51. As alleged above, pursuant to 21 CFR § 312.56, Telik was required to “review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the [clinical trial] investigator” for use in its annual reporting to the FDA. *See* ¶ 30. Moreover, as alleged in ¶ 49, during that same conference call, Defendant Butitta expressly stated that Telik designed its clinical trials to provide for interim looks, and the existence of such interim looks was re-affirmed by Defendant Wick. Thus, at the time that Defendant Wick stated that TELCYTA demonstrated a “favorable impact on survival” for ovarian cancer and non-small cell lung cancer patients, he had contrary information from the Phase 3 ASSIST-1 and ASSIST-2 trials that showed that this statement were materially misleading.

52. On December 29, 2004, the Company issued a press release announcing the initiation of ASSIST-3, a third Phase 3 clinical trial of TELCYTA. In that release, the Company explained:

ASSIST-3 is a randomized Phase 3 study designed to enroll 244 women with 122 to be treated with the combination of TELCYTA plus carboplatin, and 122 to be treated with Doxil®. The trial endpoints are objective response rate, progression-free survival and overall survival. The

study is based on a positive multicenter Phase 2 study of the combination of TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer, first presented at the annual meeting of the American Society of Clinical Oncology earlier this year and later updated at the Tenth Biennial International Gynecologic Cancer Society meeting. The initial participating institutions are the Harvard Affiliated Hospitals including the Massachusetts General Hospital, Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Beth Israel Deaconess Medical Center.

53. On January 24, 2005, the Company issued a press release entitled "Telik Announces Proposed Public Offering of Common Stock." Therein, the Company, in relevant part, stated:

Telik, Inc. (Nasdaq: TELK) today announced that it plans to file a prospectus supplement with the Securities and Exchange Commission related to an underwritten offering of 5,000,000 shares of its common stock under an existing shelf registration statement. In connection with the offering, Telik expects to grant the underwriters a 30-day option to purchase up to 750,000 additional shares to cover over-allotments, if any.

UBS Investment Bank is acting as the sole book-running manager in this offering. J.P. Morgan Securities Inc. and Lehman Brothers are acting as co-managers.

54. On February 9, 2006, the Company issued a press release entitled "Telik Announces Fourth Quarter and 2005 Year End Financial Results and 2006 Financial Guidance." The press release, in relevant part, stated:

2005 highlights included:

- **The advancement of our lead product candidate, TELCYTA®, in three randomized Phase 3 registration trials** and in two Phase 2 trials in first-line non-small cell lung cancer:
  - The ASSIST-1 Phase 3 trial completed enrollment of 440 women with platinum refractory or resistant ovarian cancer in the third-line setting. The primary endpoint for ASSIST-1 is improvement in survival.
  - \* \* \*
  - The ASSIST-3 trial was initiated to evaluate the combination of TELCYTA plus carboplatin in second-line platinum refractory or

resistant ovarian cancer. This trial is enrolling 244 women. The primary endpoint for ASSIST-3 is objective response rate as well as progression-free survival.

- The ASSIST-2 trial completed enrollment of 520 patients with platinum resistant non-small cell lung cancer in the third-line treatment setting. Improvement in survival is the primary endpoint of the ASSIST-2 trial.

55. The statements concerning the “advancement” of TELCYTA in the Phase 3 clinical trials was materially false and misleading because the Telik Defendants knowingly or recklessly failed to disclose that the ASSIST-1 and ASSIST-2 clinical trials were not advancing FDA approval of TELCYTA. In fact, the interim data, including event (death) rate data, from the Phase 3 ASSIST-1 and ASSIST-2 clinical trials of TELCYTA that the Telik Defendants had received and were continuing to receive showed **no** improvement in overall median survival – the primary endpoint for both trials – for ovarian cancer patients and non-small cell lung cancer patients, respectively, who received TELCYTA as a single agent as compared to the control arms. Indeed, it was ultimately disclosed at the end of the Class Period that ovarian cancer patients receiving TELCYTA as a single agent had a median survival rate of 8.5 months as compared to a median survival rate of 13.5 months for the patients in the control arm who did not receive TELCYTA. It was also disclosed at the end of the Class Period that the non-small cell lung cancer patients who had received TELCYTA had a median survival rate of 4.6 months compared to a median survival rate of 6.1 months for the control group that had not received TELCYTA.

56. As alleged above, pursuant to 21 CFR § 312.56, Telik was required to “review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the [clinical trial] investigator” for use in its annual reporting to the FDA. *See* ¶ 30. Moreover, Defendant Butitta expressly stated that Telik designed its clinical trials to provide for



interim looks, and the existence of such interim looks was re-affirmed by Defendant Wick. *See* ¶ 49. Thus, at the time that the Telik Defendants stated that Telik's clinical trials were advancing TELCYTA, they had contrary information from the Phase 3 ASSIST-1 and ASSIST-2 trials that showed that this statement were materially misleading.

57. In addition, the statements concerning the status of the ASSIST-3 clinical trial were materially false and misleading because the Telik Defendants knowingly or recklessly failed to disclose that numerous patients were being prematurely withdrawn from the ASSIST-3 trial due to disease progression, compromising the integrity of that trial. As alleged more fully below, in December 2006, the Company disclosed that approximately 25% of the patients enrolled in the ASSIST-3 trial were prematurely withdrawn from that trial. As a consequence, the trial data was compromised and deemed unsuitable for regulatory submission.

58. As alleged above, pursuant to 21 CFR § 312.32, Telik was required to make annual reports to the FDA in connection with its on-going clinical trials. Pursuant to 21 CFR 312.33(a)(2), Telik was required to report to the FDA, among other things, the number of patients who dropped out of the trial. *See* ¶ 31. Moreover, Defendant Butitta expressly stated that Telik designed its clinical trials to provide for interim looks, and the existence of such interim looks was re-affirmed by Defendant Wick. *See* ¶ 49. Furthermore, the Telik Defendants' failure to disclose the continuing premature withdrawal of patients from ASSIST-3 was directly contrary to Defendant Wick's April 29, 2004 statement that "we'll only communicate with the street if any of those interim looks change in a material way our guidance for that trial, either in terms of **size**, of timing, or that's [it's] finished." *See* ¶ 49 (emphasis added). Thus, at the time that the Telik Defendants reported on the status of the ASSIST-3



clinical trial, they knew or recklessly disregarded information showing that there was an unusually high drop-out rate for that trial that could, and ultimately did, compromise the trial.

59. On May 4, 2006, the Company issued a press release entitled "Telik Announces Financial Results for 2006 First Quarter." The release, in relevant part, stated:

Recent highlights include:

- Completion of ASSIST-3 enrollment: Telik announced the completion of planned enrollment for the ASSIST-3 trial, a Phase 3 trial evaluating the combination of TELCYTA plus carboplatin to treatment with Doxil in women with platinum refractory or resistant ovarian cancer.

60. The statements concerning the status of the ASSIST-3 clinical trial were materially false and misleading because the Telik Defendants knowingly or recklessly failed to disclose that numerous patients were being prematurely withdrawn from the ASSIST-3 trial due to disease progression, compromising the integrity of that trial. As alleged more fully below, in December 2006, the Company disclosed that approximately 25% of the patients enrolled in the ASSIST-3 trial were prematurely withdrawn from that trial. As a consequence, the trial data was compromised and deemed unsuitable for regulatory submission.

61. As alleged above, pursuant to 21 CFR § 312.32, Telik was required to make annual reports to the FDA in connection with its on-going clinical trials. Pursuant to 21 CFR 312.33(a)(2), Telik was required to report to the FDA, among other things, the number of patients who dropped out of the trial for any reason. *See* ¶ 30. Moreover, Defendant Butitta expressly stated that Telik designed its clinical trials to provide for interim looks, and the existence of such interim looks was re-affirmed by Defendant Wick. *See* ¶ 49. Furthermore, the Telik Defendants' failure to disclose the continuing premature withdrawal of patients from ASSIST-3 was directly contrary to Defendant Wick's April 29, 2004 statement that "we'll only communicate with the street if any of those interim looks change in a material way our guidance

for that trial, either in terms of **size**, of timing, or that's [it's] finished." See ¶ 49 (emphasis added). Thus, at the time that the Telik Defendants reported on the status of the ASSIST-3 clinical trial, they knew or recklessly disregarded information showing that there was an unusually high drop-out rate for that trial that could, and ultimately did, compromise the trial.

62. On August 3, 2006, the Company issued a press release entitled "Telik Announces Quarterly Financial Release, Conference Call and Webcast." Therein, the Company, in relevant part, stated:

Developments during the second quarter of 2006 included:

- Completion of patient enrollment in the ASSIST-3 Phase 3 clinical trial, which will compare treatment with the combination of TELCYTA and carboplatin to treatment with liposomal doxorubicin, also in the second line setting in women with platinum refractory or resistant ovarian cancer.

63. The statements concerning the status of the ASSIST-3 clinical trial were materially false and misleading because the Telik Defendants knowingly or recklessly failed to disclose that numerous patients were being prematurely withdrawn from the ASSIST-3 trial due to disease progression, compromising the integrity of that trial. As alleged more fully below, in December 2006, the Company disclosed that approximately 25% of the patients enrolled in the ASSIST-3 trial were prematurely withdrawn from that trial. As a consequence, the trial data was compromised and deemed unsuitable for regulatory submission.

64. As alleged above, pursuant to 21 CFR § 312.32, Telik was required to make annual reports to the FDA in connection with its on-going clinical trials. Pursuant to 21 CFR 312.33(a)(2), Telik was required to report to the FDA, among other things, the number of patients who dropped out of the trial. See ¶ 31. Moreover, Defendant Butitta expressly stated that Telik designed its clinical trials to provide for interim looks, and the existence of such interim looks was re-affirmed by Defendant Wick. See ¶ 49. Furthermore, the Telik

Defendants' failure to disclose the continuing premature withdrawal of patients from ASSIST-3 was directly contrary to Defendant Wick's April 29, 2004 statement that "we'll only communicate with the street if any of those interim looks change in a material way our guidance for that trial, either in terms of **size**, of timing, or that's [it's] finished." See ¶ 49 (emphasis added). Thus, at the time that the Telik Defendants reported on the status of the ASSIST-3 clinical trial, they knew or recklessly disregarded information showing that there was an unusually high drop-out rate for that trial that could, and ultimately did, compromise the trial.

## **II. The Truth is Partially Disclosed**

65. On December 26, 2006, the Company issued a press release entitled "Telik Reports Preliminary Results on ASSIST-1, ASSIST-2 and ASSIST-3 Phase 3 Clinical Trials." This press release disclosed that all three of the Company's clinical trials had failed. The press release, in relevant part, stated:

Telik, Inc. (Nasdaq: TELK) announced preliminary results from three separate Phase 3 clinical trials of its investigational drug TELCYTA (TLK286, canfosfamide HCl).

### **Non-Small Cell Lung Cancer**

#### **ASSIST-2 Trial**

The ASSIST-2 trial, a 520 patient multinational, randomized study designed to evaluate TELCYTA as compared to gefitinib in the third-line therapy of advanced non-small cell lung cancer, *did not achieve a statistically significant improvement in overall survival, the primary endpoint.*

### **Platinum Refractory or Resistant Ovarian Cancer**

#### **ASSIST-1 Trial**

The ASSIST-1 trial, a 440 patient multinational, randomized study designed to evaluate TELCYTA as compared to the active control agents liposomal doxorubicin or topotecan in the third-line therapy of platinum resistant ovarian cancer, *did not achieve its primary endpoint of demonstrating a statistically significant improvement in overall survival*

*for TELCYTA as compared to the active controls.* While the preliminary analysis revealed a number of internal inconsistencies that need to be further investigated, resolution of these inconsistencies may not change the preliminary results.

### **ASSIST-3 Trial**

The ASSIST-3 trial, a 244 patient randomized trial conducted in the U.S., was designed to demonstrate a statistically significant improvement in overall tumor response to the combination of TELCYTA plus carboplatin compared to liposomal doxorubicin in the second-line treatment of platinum resistant ovarian cancer. Under the trial protocol, patients were to have received treatment until tumor progression or unacceptable toxicity. However, a major discordance was observed between the clinical review of the tumor scans and the independent radiology review.

*Approximately 25% of the patients were discontinued prematurely from the assigned study treatment as judged by the independent review of the scans. Therefore, the company believes the trial was compromised and may not be suitable for a regulatory submission.* The company plans to meet with advisors to review the results and also to determine if any changes should be made to the protocol and/or trial conduct procedures for the ongoing ASSIST-5 trial. [Emphasis added.]

66. After announcement, Telik shares plummeted \$11.49 per share, or over 70%, to close on December 26, 2006 at \$4.77 per share, on unusually heavy trading volume.

67. Although partially curative of the materially misleading statements made during the previous part of the Class Period, the Telik Defendants' statements concerning the failure of the ASSIST-1 and ASSIST-2 Phase 3 clinical trials were, nonetheless, also materially false and misleading. While the Telik Defendants disclosed that TELCYTA did not reach the primary endpoints – improvement in survival – in either ASSIST-1 or ASSIST-2, they knowingly or recklessly failed to disclose that patients who received TELCYTA in ASSIST-1 and ASSIST-2 actually had median survival rates that were **lower** than the patients in the control arms that did not receive the drug. Indeed, it was ultimately disclosed at the end of the Class Period that ovarian cancer patients receiving TELCYTA as a single agent had a median survival rate of 8.5 months as compared to a median survival rate of 13.5 months for the patients in the control arm

who did not receive TELCYTA. It was also disclosed at the end of the Class Period that the non-small cell lung cancer patients who had received TELCYTA had a median survival rate of 4.6 months compared to a median survival rate of 6.1 months for the control group that had not received TELCYTA.

68. Moreover, that the Telik Defendants were able to conclude that the patients who received TELCYTA showed no improved survivability compared to those who did not, demonstrates that the Telik Defendants knew and compared the actual median survival rates for these patients. Despite that knowledge, the Telik Defendants attempted to minimize the adverse impact of the clinical trial findings by failing to disclose that patients who administered their drug died at a materially faster rate than those who were not.

69. Defendants held a conference call with analysts on the same day the clinical trial findings were announced. During the call, the Telik Defendants, in a complete retreat from their earlier pre-Class Period and Class Period statements, claimed that the Phase 3 trials were blinded, and that they had no interim data about the trial. In addition, when an analyst asked “Okay, was there any, in terms of ASSIST-1, 2, or 3, any magnitude differences to suggest some benefit of TELCYTA over the comparator arms?”, Dr. Gail Brown, Telik’s Chief Medical Officer and wife of Defendant Wick, stated, “I am not prepared to discuss that today. We have to do further analysis of all the trials.”

70. Dr. Brown’s statement was materially false and misleading because she and the Telik Defendants knowingly or recklessly failed to disclose that the Telik defendants had already determined that patients who received TELCYTA in ASSIST-1 and ASSIST-2 actually had median survival rates that were **lower** than the patients in the control arms that did not receive the drug. Indeed, it was ultimately disclosed at the end of the Class Period that ovarian cancer

patients receiving TELCYTA as a single agent had a median survival rate of 8.5 months as compared to a median survival rate of 13.5 months for the patients in the control arm who did not receive TELCYTA. It was also disclosed at the end of the Class Period that the non-small cell lung cancer patients who had received TELCYTA had a median survival rate of 4.6 months compared to a median survival rate of 6.1 months for the control group that had not received TELCYTA.

71. Notably, on January 12, 2007, Wachovia Capital Markets, who followed Telik throughout the Class Period, published an analyst report stating that, after the disclosures of December 26, 2006, they expected “a newly humbled management – aware of the necessity for more open disclosure...”

72. On April 17, 2007 and May 3, 2007, the Company issued press releases announcing positive data from a Phase 2 trial of TELCYTA in combination with carboplatin and paclitaxel in the first-line treatment of advanced non-small cell lung cancer. However, the Telik Defendants made no new announcements concerning the results of the ASSIST-1, ASSIST-2 or ASSIST-3 Phase 3 clinical trials for more than five months after the initial December 26, 2006 announcement.

### **THE FULL TRUTH IS FINALLY DISCLOSED**

73. Finally, on June 3, 2007, the Company announced the results of its ASSIST-1 trial at the ASCO annual meeting. In stark contrast to the Company's prior statements, the Company revealed for the first time that participants in the ASSIST-1 Phase 3 clinical trial who received TELCYTA actually died sooner – an average of five months sooner – than those who did not receive the drug. In an *Associated Press* release, the Company, in relevant part, revealed:

Telik, Inc. (Nasdaq: TELK) reported results of the TELCYTA (canfosfamide HCl, TLK286) ASSIST-1 trial today at the 43rd annual meeting of the American Society of Clinical Oncology (ASCO).

The Phase 3, international, randomized, active control study enrolled 461 women with advanced, platinum refractory or resistant ovarian cancer whose disease had progressed following first-line platinum-based therapy and second-line treatment with either liposomal doxorubicin or topotecan. Two hundred thirty-two women were randomized to TELCYTA treatment and 229 women were randomized to treatment with one of the active control drugs (pegylated liposomal doxorubicin (PLD) or topotecan), depending upon their second-line treatment. The two arms of the study were balanced for key ovarian cancer disease characteristics, platinum refractory or resistant status, and other prognostic or predictive factors.

The trial did not meet the primary endpoint of demonstrating superiority in overall survival or the secondary endpoint of demonstrating superiority in progression-free survival on the TELCYTA arm as compared with the active control arm. **Median survival on the TELCYTA arm was 8.5 months compared with 13.6 months on the active control arm (p <0.01). Median progression-free survival was 2.3 months on the TELCYTA arm compared with 4.3 months on the active control arm.** [Emphasis added.]

74. In a separate press release on that same day, June 3, 2007, Telik announced the results of its ASSIST-2 Phase 3 clinical trial:

Telik, Inc. (Nasdaq: TELK) announced top-line results from the ASSIST-2 Phase 3 study of TELCYTA (canfosfamide HCl, TLK286) versus gefitinib in the third-line treatment of non-small cell lung cancer (NSCLC).

The Phase 3, international, randomized, active control study enrolled 530 patients with advanced NSCLC whose disease had progressed following first-line platinum-based therapy and a second-line treatment. Two hundred sixty-five patients were randomized to TELCYTA treatment and 265 patients were randomized to gefitinib. The two arms of the study were balanced for key NSCLC disease characteristics and other prognostic or predictive factors.

The trial did not meet the primary endpoint of demonstrating superiority in overall survival or the secondary endpoint of demonstrating superiority in progression-free survival for the TELCYTA arm as compared with gefitinib. **Median survival for the TELCYTA arm was 4.6 months as compared with 6.1 months for the active control arm. Median**



**progression-free survival was 2.2 months for the TELCYTA arm as compared with 2.3 months for the gefitinib arm. [Emphasis added.]**

75. On June 3, 2007, the Company also issued a press release announcing the results of it the ASSIST-3 Phase 3 clinical trial:

Telik, Inc. (Nasdaq: TELK) reported results of the TELCYTA (canfosfamide HCl, TLK286) ASSIST-3 trial today at the 43rd annual meeting of the American Society of Clinical Oncology (ASCO).

The Phase 3, randomized, active control study enrolled 247 women with advanced, platinum refractory or resistant ovarian cancer whose disease had progressed following first-line platinum-based therapy. One hundred twenty-three women were randomized to treatment with the combination of TELCYTA and carboplatin and 124 women were randomized to treatment with pegylated liposomal doxorubicin (PLD). The two arms of the study were balanced for key ovarian cancer disease characteristics, platinum refractory or resistant status, and other prognostic or predictive factors. All patients had platinum refractory or resistant disease, with a platinum-free interval (PFI, from the date of last treatment with platinum-based chemotherapy to the date of documented disease progression) of six months or less.

Patients were treated until disease progression, as determined by radiologic evaluations at each site, or unacceptable toxicity. A central, blinded independent radiology review also was conducted.

**Assessment of the primary endpoint, objective response rate by RECIST, may have been compromised because approximately 25% of patients were prematurely discontinued from the study for disease progression, as assessed by the independent radiology review. [Emphasis added.]**

76. On June 4, 2007, the Company announced that the FDA had placed a clinical hold on the Company's Investigational New Drug application for TELCYTA. The clinical hold was initiated by the FDA following the presentation of TELCYTA Phase 3 clinical trial results. The effect of this clinical hold stopped new patient enrollment in TELCYTA clinical trials, and the Company was prohibited from administering additional doses of the drug to those patients already enrolled in the trials. In an *Associated Press* release, the Company, in relevant part, stated:



Telik, Inc. (Nasdaq: TELK) announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on the Investigational New Drug (IND) application for TELCYTA® (canfosfamide HCl). The clinical hold was initiated by FDA following the presentation of TELCYTA Phase 3 clinical trial results at the annual meeting of the American Society of Clinical Oncology.

No new patients will be enrolled on TELCYTA clinical trials, and no patients currently being treated on the trials will receive additional treatment until the FDA releases the clinical hold. Telik plans to submit to the FDA additional detailed safety and other information regarding TELCYTA and meet with the FDA regarding the clinical hold as soon as possible.

77. Following the Company's news and the FDA announcement, shares of the Company's stock declined an additional 41% to close on June 5, 2007 at \$3.42 per share, on unusually heavy trading volume.

#### **POST-CLASS PERIOD DEVELOPMENTS**

78. On June 5, 2007, Wachovia Capital Markets, which followed Telik closely throughout the Class Period, stated:

**Scrutinizing management credibility.** Nevertheless, we view this as a disturbing development to our TELK investment thesis, which we believed had been maximally hindered following the failure of ASSIST 1, 2, and 3 clinical trials going into ASCO. This major blow now calls into question management's judgment and its ability to responsibly develop TELCYTA not only in the interest of shareholders but also in the interest of patients as well, in our view. [Emphasis in original].

79. On June 13, 2007, the following article was published on *thestreet.com*:

The Food and Drug Administration has launched an inquiry to determine whether Telik violated federal law by failing to disclose patient deaths in a recent ovarian cancer study, *TheStreet.com* has learned.

Women taking Telik's experimental drug Telcyta died five months faster than similar women in the study's control arm, according to data presented publicly for the first time on June 3 at the annual meeting of the American Society of Clinical Oncology.

But Telik's management knew since December 2006 -- five months before presenting the data at ASCO -- that Telcyta might be harming ovarian cancer patients instead of helping them. This information was never publicly disclosed.

Furthermore, Telik failed to share the data with the FDA, according to a senior official with the agency.

Concerned for patient safety, the FDA ordered Telik last week to halt all ongoing clinical studies involving Telcyta.

"It is unclear to us at this point whether regulations or laws may have been broken, but we're looking into the matter seriously," said the FDA official, who asked to remain unnamed.

"Sophisticated companies would have reported data like this to us in a timely manner," the FDA official added. "The fact that we learned of this [the Telcyta patient deaths] at the ASCO meeting will adversely affect the company in the future because we can't trust them." [...]

Shortly after the December announcement, [Salway] Black says her group sent Telik a letter asking for more details about the Assist-1 study so that it could make sure that the company was sharing all relevant information with ovarian cancer patients.

"We never got a response to our letter," says Salway Black, adding that the first she heard of the Telcyta patient deaths was after the data were made public at the ASCO meeting.

"I think this information definitely should have been distributed sooner," she says.

#### **SUBSTANTIVE ALLEGATIONS UNDER THE SECURITIES ACT**

80. In January 2005, the Company conducted a follow-on offering (the "2005 Offering"), pursuant to a Registration Statement filed in April 2004, incorporating therein a Prospectus Supplement, filed with the SEC on January 28, 2005 (the "2005 Prospectus"). The 2005 Prospectus indicated that the Company sought to sell 7 million shares of stock to the public at \$18.75 per share, with an underwriter over-allotment of an additional 1.05 million shares for sale. The 2005 Offering was underwritten by the Underwriting Defendants.

81. In the 2005 Prospectus, the Company stated:

TELCYTA, our lead product candidate, is a small molecule tumor-activated cancer product candidate that binds to glutathione S-transferase P1-1, or GST P1-1, a protein that is elevated in many human cancers, such as ovarian, non-small cell lung, colorectal, breast and other types of cancer. GST P1-1 levels are often further elevated following treatment with many standard chemotherapy drugs, and this elevation is associated with the development of resistance to these drugs. When TELCYTA binds to GST P1-1 inside a cancer cell, a chemical reaction occurs, releasing fragments of TELCYTA that cause programmed cancer cell death, or apoptosis.

**TELCYTA has shown clinical antitumor activity alone and in combination in multiple Phase 2 clinical trials in refractory or resistant ovarian, non-small cell lung, breast and colorectal cancer. Positive results from three combination trials** were presented at the annual meeting of the American Society of Clinical Oncology in June 2004 and at the Tenth Biannual International Gynecologic Cancer Society meeting in October 2004. [Emphasis added.]

82. The statements concerning the antitumor effect of TELCYTA and the positive results of the multiple Phase 2 clinical trials were materially misleading because the 2005 Prospectus failed to disclose that interim data on the on-going ASSIST-1 and ASSIST-2 Phase 3 clinical trials of TELCYTA showed that patients who received TELCYTA died **sooner** than the patients in the control arms of those trials, who did not receive TELCYTA.

83. The 2005 Offering was a financial success for the Company, as it was able to raise over \$150.9 million in gross proceeds.

#### **PLAINTIFFS' CLASS ACTION ALLEGATIONS**

84. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Telik's common stock between February 19, 2004 and June 4, 2007, inclusive, including purchasers in the Company's January 28, 2005 stock offering, seeking to pursue remedies under the Securities Act and the Exchange Act.

85. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Telik's common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Telik or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

86. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

87. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

88. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Telik; and
- c) to what extent the members of the Class have sustained damages and the proper measure of damages.

89. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **UNDISCLOSED ADVERSE FACTS**

90. The market for Telik's common stock was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Telik's common stock traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Telik's common stock relying upon the integrity of the market price of Telik's common stock and market information relating to Telik, and have been damaged thereby.

91. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Telik's common stock, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

92. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading

statements about Telik's principal product TELCYTA and the results of the FDA clinical trials conducted in connection therewith. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Telik and its financial well-being, business relationships, and prospects, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's common stock at artificially inflated prices, thus causing the damages complained of herein.

### **LOSS CAUSATION**

93. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

94. During the Class Period, Plaintiffs and the Class purchased common stock of Telik at artificially inflated prices and were damaged thereby. The price of Telik's common stock significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

### **SCIENTER ALLEGATIONS**

95. With respect to Plaintiffs' Exchange Act claims as alleged herein, the Telik Defendants acted with scienter because they: knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth

elsewhere herein in detail, the Telik Defendants, by virtue of their receipt of information reflecting the true facts regarding the Phase 3 clinical trials of TELCYTA, their control over, and/or receipt and/or modification of Telik's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Telik, participated in the fraudulent scheme alleged herein.

96. As alleged above, as sponsor of pharmaceutical clinical trials, Telik was required to monitor the progress of the ASSIST-1, ASSIST-2 and ASSIST-3 clinical trials of TELCYTA. 21 CFR § 312.56. In addition, Telik was required to make periodic reports to the FDA concerning the status of those trials. *Id.*; 21 CFR 312.33. Among the information that Telik was required to report to the FDA was “if interim results are known, a brief description of any available study results,” as well as “[a] list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.” 21 CFR 312.33 (a)(3), (b)(4). As a consequence of these regulatory requirements, the Telik Defendants were privy to non-public information about the survival rates of patients in the ASSIST-1 and ASSIST-2 clinical trials, as well as the premature withdrawal of patients in the ASSIST-3 trial.

97. In addition, the Telik Defendants apprised analysts and investors that the clinical trials were designed to provide “interim looks.” Indeed, prior to, and throughout the Class Period, the Telik Defendants issued public statements about the positive interim results of various Phase 2 clinical trials involving TELCYTA, as alleged above.

98. Despite the Telik Defendants’ receipt of adverse interim data concerning survival rates in the ASSIST-1 and ASSIST-2 trials, the Telik Defendants made materially false and misleading statements about TELCYTA’s purported favorable impact on survival rates for



ovarian and non-small cell lung cancer patients throughout the Class Period. In addition, the Telik Defendants failed to disclose the unusually high premature withdrawal rate of patients in the ASSIST-3 trial, despite the fact that in an April 29, 2004 conference call with analysts and investors, Defendant Wick stated that the Company would communicate with the market “if any of those interim looks change in a material way our guidance for that trial, either in terms of size, of timing, or that's [it's] finished.” See ¶ 49 (emphasis added).

99. The Telik Defendants were motivated to conceal the adverse facts about the TELCYTA Phase 3 clinical trials in order to successfully complete the 2005 Offering, in which the Company offered 8.05 million shares of common stock to the public at the artificially inflated price of \$18.75 per share, for gross proceeds of over \$150.9 million.

100. Even after the Telik Defendants disclosed that TELCYTA had failed to reach the primary endpoint in the ASSIST-1, ASSIST-2, or ASSIST-3 trials, they failed to disclose the full extent of the adverse information about TELCYTA, namely that the patients treated with the drug died sooner than those who did not receive it. As alleged above, in order to determine whether TELCYTA improved survival rates – the primary endpoints in ASSIST-1 and ASSIST-2 – it was necessary for the Telik Defendants to compare the survival rates of patients receiving TELCYTA and those who did not. The Telik Defendants, therefore, clearly knew, but failed to disclose that the TELCYTA-treated patients died earlier than the control groups in the ASSIST-1 and ASSIST-2 trials. Despite that, the Telik Defendants did not disclose this information for more than five months, until June 2007.

**Applicability of Presumption of Reliance:  
Fraud On The Market Doctrine**

101. At all relevant times, the market for Telik's common stock was an efficient market for the following reasons, among others:



- a) Telik's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b) As a regulated issuer, Telik filed periodic public reports with the SEC and the NASDAQ;
- c) Telik regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- d) Telik was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

102. As a result of the foregoing, the market for Telik's common stock promptly digested current information regarding Telik from all publicly-available sources and reflected such information in Telik's stock price. Under these circumstances, all purchasers of Telik's common stock during the Class Period suffered similar injury through their purchase of Telik's common stock at artificially inflated prices and a presumption of reliance applies.

#### **NO SAFE HARBOR**

103. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no

meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Telik who knew that those statements were false when made.

### **FIRST CLAIM**

#### **Violation of Section 11 of The Securities Act Against All Defendants**

104. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the Defendants to defraud Plaintiffs or members of the Class. This count is predicated upon Defendants' strict liability for making false and materially misleading statements in the Prospectus.

105. This claim is asserted by Plaintiffs against all Defendants by, and on behalf of, persons who acquired shares of the Company's common stock pursuant to or traceable to the Prospectus issued in connection with the Company's January 2005 Offering.

106. The Individual Defendants, as signatories of the Registration Statement and Prospectus, as directors and/or officers of Telik and controlling persons of the issuer, owed to the holders of the stock obtained through the 2005 Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the 2005 Prospectus at the time they became effective to ensure that such statements were true and correct, and that there was no omission of

material facts required to be stated in order to make the statements contained therein not misleading. Defendants knew, or in the exercise of reasonable care should have known, of the material misstatements and omissions contained in or omitted from the 2005 Prospectus as set forth herein. As such, Defendants are liable to the Class.

107. The Underwriter Defendants owed to the holders of the stock obtained through the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the 2005 Prospectus at the time they became effective to ensure that such statements were true and correct and that there was no omission of material facts required to be stated in order to make the statements contained therein not misleading. The Underwriter Defendants knew, or in the exercise of reasonable care should have known, of the material misstatements and omissions contained in or omitted from the 2005 Prospectus as set forth herein. As such, the Underwriter Defendants are liable to the Class.

108. None of the Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the 2005 Prospectus were true or that there was no omission of material facts necessary to make the statements made therein not misleading.

109. Defendants issued and disseminated, caused to be issued and disseminated, and participated in the issuance and dissemination of, material misstatements to the investing public which were contained in the 2005 Prospectus, which misrepresented or failed to disclose, *inter alia*, the facts set forth above. By reason of the conduct herein alleged, each Defendant violated and/or controlled a person who violated Section 11 of the Securities Act.

110. As a direct and proximate result of Defendants' acts and omissions in violation of the Securities Act, the market price of Telik's common stock sold in the Offering was artificially

inflated, and Plaintiff and the Class suffered substantial damage in connection with their purchase of Telik's common stock pursuant to the 2005 Prospectus.

111. Telik is the issuer of the stock sold via the 2005 Prospectus. As issuer of the stock, the Company is strictly liable to Plaintiffs and the Class for the material misstatements and omissions therein.

112. At the times they obtained their shares of Telik, Plaintiffs and members of the Class did so without knowledge of the facts concerning the misstatements or omissions alleged herein.

113. This action is brought within one year after discovery of the untrue statements and omissions in and from the 2005 Prospectus which should have been made through the exercise of reasonable diligence, and within three years of the effective date of the 2005 Prospectus.

114. By virtue of the foregoing, Plaintiffs and the other members of the Class are entitled to damages under Section 11 as measured by the provisions of Section 11(e), from the Defendants.

## **SECOND CLAIM**

### **Violation of Section 12(a)(2) of The Securities Act Against All Defendants**

115. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the Defendants to defraud Plaintiffs or members of the Class.

116. This Count is brought pursuant to Section 12(a)(2) of the Securities Act on behalf of the Class, against all Defendants.

117. Defendants were sellers, offerors, and/or solicitors of purchasers of the shares offered pursuant to the 2005 Prospectus.

118. The 2005 Prospectus contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and concealed and failed to disclose material facts. The Individual Defendants' actions of solicitation included participating in the preparation of the false the misleading 2005 Prospectus.

119. Defendants owed to the purchasers of Telik's common stock, including Plaintiffs and other members of the Class, the duty to make a reasonable and diligent investigation of the statements contained in the Offering materials, including the 2005 Prospectus, to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants knew of, or in the exercise of reasonable care should have known of, the misstatements and omissions contained in the Offering materials as set forth above.

120. Plaintiffs and other members of the Class purchased or otherwise acquired Telik's common stock pursuant to and/or traceable to the defective 2005 Prospectus. Plaintiffs did not know, or in the exercise of reasonable diligence could not have known, of the untruths and omissions contained in the 2005 Prospectus.

121. Plaintiffs, individually and representatively, hereby offers to tender to Defendants that common stock which Plaintiffs and other Class members continue to own, on behalf of all members of the Class who continue to own such common stock, in return for the consideration paid for that common stock together with interest thereon. Class members who have sold their Telik common stock are entitled to rescissory damages.

122. By reason of the conduct alleged herein, these Defendants violated, and/or controlled a person who violated Section 12(a)(2) of the Securities Act. Accordingly, Plaintiffs and members of the Class who hold Telik's common stock purchased in the Offering have the

right to rescind and recover the consideration paid for their Telik common stock, and hereby elect to rescind and tender their Telik common stock to the Defendants sued herein. Plaintiffs and Class members who have sold their Telik common stock are entitled to rescissory damages.

123. This action is brought within three years from the time that the common stock upon which this Count is brought was sold to the public, and within one year from the time when Plaintiffs discovered or reasonably could have discovered the facts upon which this Count is based.

### **THIRD CLAIM**

#### **Violation of Section 15 of The Securities Act Against the Individual Defendants**

124. Plaintiffs repeat and reallege each and every allegation contained above, excluding all allegations above that contain facts necessary to prove any elements not required to state a Section 15 claim, including without limitation, scienter.

125. This count is asserted against Individual Defendants and is based upon Section 15 of the Securities Act.

126. Individual Defendants, by virtue of their offices, directorship and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Telik within the meaning of Section 15 of the Securities Act. The Individual Defendants had the power and influence and exercised the same to cause Telik to engage in the acts described herein.

127. The Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiffs and the Class.

128. By virtue of the conduct alleged herein, the Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiffs and the Class for damages suffered.

**FOURTH CLAIM**

**Violation of Section 10(b) of The Exchange Act and Rule 10b-5**  
**Promulgated Thereunder Against All Defendants**

129. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

130. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Telik's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

131. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Telik's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

132. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Telik's financial well-being, business relationships, and prospects, as specified herein.

133. These Defendants employed devices, schemes and artifices to defraud, while in possession of material, adverse, non-public information and engaged in acts, practices, and a



course of conduct as alleged herein in an effort to assure investors of Telik's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Telik and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Telik's common stock during the Class Period.

134. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of his or her responsibilities and activities as a senior officer and/or director of the Company was privy to adverse interim data about the Company's ASSIST-1, ASSIST-2 and ASSIST-3 Phase 3 TELCYTA clinical trials; and (iii) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

135. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the adverse interim data from the ASSIST-1, ASSIST-2 and ASSIST-3 Phase 3 clinical trials of TELCYTA, Telik's principal developmental

drug, from the investing public and supporting the artificially inflated price of its common stock. As demonstrated by Defendants' material misstatements about TELCYTA throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

136. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Telik's common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Telik's common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or in the absence of material, adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Telik's common stock during the Class Period at artificially high prices and were damaged thereby.

137. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the truth about TELCYTA and Telik, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Telik common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices which they paid.

138. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

139. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

### **FIFTH CLAIM**

#### **Violation of Section 20(a) of The Exchange Act Against the Individual Defendants**

140. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

141. The Individual Defendants acted as controlling persons of Telik within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

142. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

143. As set forth above, the Telik Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

**WHEREFORE**, Plaintiffs pray for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding rescissory and/or compensatory damages in favor of Plaintiffs and the other Class members against all Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury.

Dated: New York, New York  
October 22, 2007

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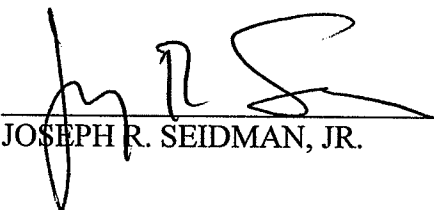
**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the attached was served upon the following counsel of record in the actions filed this Court, First Class Mail prepaid, this 22<sup>nd</sup> day of October 2007:

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